

Drug Regulatory Affairs

Foradil<sup>®</sup> Aerolizer<sup>®</sup>  
(formoterol fumarate inhalation powder) 12 mcg

Pulmonary-Allergy Drugs Advisory Committee on the safety of  
long-acting beta-agonist bronchodilators

NDA 20-831

**Appendix 2 - AE terms from FDA AERS**

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## 1 Case definition

### Asthma

'Asthma', 'Asthma exercise induced', 'Asthma late onset', 'Bronchial hyperactivity', 'Bronchial obstruction', 'Bronchial oedema', 'Bronchospasm', 'Bronchospasm paradoxical', 'Bronchostenosis', 'Chronic obstructive airways disease', 'Chronic obstructive airways disease exacerbated', 'Infantile asthma', 'Obliterative bronchiolitis', 'Obstructive airways disorder', 'Reversible airways obstruction', 'Status asthmaticus', 'Wheezing'

'Dyspnoea', 'Dyspnoea at rest', 'Dyspnoea exacerbated', 'Dyspnoea exertional', 'Dyspnoea paroxysmal nocturnal', 'Nocturnal dyspnoea', 'Respiratory arrest', 'Tachypnoea'

'Acute respiratory failure', 'Cyanosis central', 'Hypocapnia', 'Hypoxia', 'Intercostal retraction', 'Nasal flaring', 'Respiratory alkalosis', 'Respiratory distress', 'Respiratory failure', 'Supraclavicular retraction', 'Xyphoid retraction'

### COPD

'Bronchospasm', 'Bronchospasm paradoxical', 'Bronchostenosis', 'Chronic obstructive airways disease', 'Chronic obstructive airways disease exacerbated', 'Reversible airways obstruction', 'Wheezing'

'Dyspnoea', 'Dyspnoea at rest', 'Dyspnoea exacerbated', 'Dyspnoea exertional', 'Dyspnoea paroxysmal nocturnal', 'Nocturnal dyspnoea', 'Prolonged expiration', 'Respiratory arrest', 'Tachypnoea'

'Acute respiratory failure', 'Chronic respiratory failure', 'Cyanosis central', 'Dependence on respirator', 'Hypercapnia', 'Intercostal retraction', 'Nasal flaring', 'Respiratory alkalosis', 'Respiratory distress', 'Respiratory failure', 'Supraclavicular retraction', 'Xyphoid retraction'